

Program Requirements Document Companywide	12.1 CONTROL OF MEASURING AND TEST EQUIPMENT	Identifier: PRD-5083 Revision: 3 Page: 1 of 5
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Manual: 13A—Quality and Requirements
Management Program Documents

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1. PURPOSE

This Program Requirements Document (PRD) identifies requirements and responsibilities for controlling *measuring and test equipment* (M&TE; see def.). See Appendix A for requirements basis.

2. APPLICABILITY

This PRD applies to company organizations that use or calibrate measuring and test equipment for determining *acceptance* (see def.) of *items* (see def.) and activities, process monitoring, or *data* (see def.) collection. The *calibration* (see def.) program applies to all calibration activities that are encompassed by DOE Order 4330.4B, Maintenance Management Program, DOE O 414.1, Quality Assurance, 10 CFR 830 Subpart A, Quality Assurance Requirements, and 10 CFR 835, Occupational Radiation Protection.

Calibration and control measures are not applicable for rulers, tape measures, levels, and other such coarse measurement devices that provide adequate accuracy as received from the manufacturer.

3. RESPONSIBILITIES

3.1 Organizations

Organizations using, calibrating, and maintaining M&TE, or procuring or requesting calibration services are responsible for implementing the requirements of this document as they apply to their functions.

3.2 Senior Management

Senior management is responsible for ensuring that the calibration program and laboratory management staff has the authority and sufficient resources to discharge their duties.

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3.3 Calibration Organizations

The calibration organizations, which include the Standards and Calibration Laboratories and Health Physics Instrumentation Laboratory, are the *standards* (see def.) laboratories for the INEEL. The responsibilities of these organizations include:

- A. Providing technical *guidance* (see def.), *training* (see def.), and consultation as requested.
- B. Ensuring a properly balanced calibration program and measurement compatibility through a measurement technology developmental program that will enable the timely provision of new *measurement standards* (see def.) and M&TE.
- C. Providing development, maintenance and/or specification of primary standards.
- D. Providing *certification* (see def.) of *reference standards* (see def.).

4. REQUIREMENTS

4.1 Companywide Application

The requirements identified in this subsection (4.1) apply to the entire company unless exempted by INT-17, QA PRD Introduction, Subsection 2.

4.1.1 Basic

- 4.1.1.1 M&TE requiring calibration shall include instruments or equipment used for *testing* (see def.), *inspection* (see def.), calibration of other instruments, process *verification* (see def.), or data collection for purposes of determining compliance with customer requirements. *[Summary of calibration requirements of NQA-1-1997, DOE/RW-0333P, and ANSI/NCSS Z540]*
- 4.1.1.2 Tools, gages, instruments, and other measuring and test equipment used for *activities affecting quality* (see def.) shall be controlled, calibrated at specific intervals, adjusted, and maintained to required accuracy limits. *[NQA-1-1997, Requirement 12, 100]*
- 4.1.1.3 Calibration program implementing documents, such as management control *procedures* (see def.) and technical procedures, shall address the requirements contained in the following calibration program standards. *[Company response to DOE Order 414.1A, Attachment-1, 1.a(4) and CFR 830. 121, (c)(3)]*

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- A. ANSI/NCSL Z540-1-1994, American National Standard for Calibration-Calibration Laboratories and Measuring and Test Equipment-General Requirements *[Company response to DOE Order 414.1A, Attachment-1, 1.a(4) and CFR 830.121, (c)(3)]*
- B. ANSI N323A-1997, American National Standard Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments. *[Company response to DOE Order 414.1A, Attachment-1, 1.a(4) and CFR 830.121, (c)(3)]*

NOTE 1: *The detailed calibration program requirements contained in ANSI/NCSL Z540-1-1994 satisfy the requirements of NQA-1-1997 and DOE/RW-0333P. (Reference letter TS-QAD-00-149.) Therefore the requirements of NQA-1 and DOE-RW-0333P are not restated in this document except for the requirements that are not sufficiently addressed by ANSI/NCSL Z540-1-1994.*

NOTE 2: *Copies of ANSI/NCSL Z540-1-1994 and ANSI N323A-1997 may be obtained by contacting the Calibration Program Office at 6-6285.*

- 4.1.1.4 The implementing documents shall address the additional requirements of DOE/RW-0333P as listed below. *[Company response to DOE Order 414.1A, Attachment-1, 1.a(4) and CFR 830.121, (c)(3)]*

4.1.2 Controlling Measuring and Test Equipment

- 4.1.2.1 Measuring and test equipment, including equipment that contains *software* (see def.) or programmable hardware, shall be calibrated, adjusted, and maintained as a unit at prescribed intervals, software changes, or prior to use, against reference calibration standards having *traceability* (see def.) to nationally recognized standards. *[DOE/RW-0333P 12.2.1.A.1s and 12.2.1.G]*
- 4.1.2.2 For measuring and test equipment used in one-time-only applications, the calibration shall be done both before and after use. *[DOE/RW-0333P 12.2.1.C.2s]*
- 4.1.2.3 When measuring and test equipment is found out of tolerance or lost, the validity of results obtained using that equipment since its last valid calibration shall be evaluated. The evaluation shall be documented and include the determination of acceptability for previously collected data, processes monitored, or items previously inspected or tested. *[DOE/RW-0333P 12.2.4, 12.2.4.A, and 12.2.4.B]*

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4.1.2.4 Software developed or modified by the user shall be controlled in accordance with DOE/RW-0333P Supplement I, Software.
[DOE/RW-0333P 12.2.1.A.2s]

4.1.2.5 The use of measuring and test equipment shall be documented. As appropriate to equipment use and its calibration schedule, the documentation shall identify the processes monitored, data collected, or items inspected or tested since the last calibration.
[DOE/RW-0333P 12.2.2.1s and 12.2.2.2s]

4.1.3 Records

4.1.3.1 All records designated in implementing documents as *quality assurance records* (see def.) shall be controlled in accordance with PRD-5088, 17.1 Quality Assurance Records. [Summary of records requirements from NQA-1-1997, DOE/RW-0333P, and Company Imposed Requirements]

5. DEFINITIONS

Refer to LST-199, Definitions, in the QA PRD Manual for the definitions of the following terms:

acceptance

activities affecting quality

calibration

certification

data

guidance

inspection

item

measuring and test equipment

measurement standard

procedure

quality assurance records

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reference standard

software

standards

testing

traceability (calibration)

training

verification

6. REFERENCES

10 CFR 830 Subpart A, Quality Assurance

10 CFR 835, Occupational Radiation Protection

ANSI/N323A-1997, American National Standard Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments.

ANSI/NCSL Z540-1-1994, American National Standard for Calibration—Calibration Laboratories and Measuring and Test Equipment—General Requirements

ASME NQA-1-1997, Quality Assurance Requirements for Nuclear Facility Applications

DOE Order 414.1A, Quality Assurance

DOE Order 4330.4E, Maintenance Management Program, 1994

DOE/RW-0333P, Office of Civilian Radioactive Waste Management, Quality Assurance Requirements and Description, Revision 10

TS-QAD-00-146, DOE-ID Robert D. Davis letter to distribution, Use of Voluntary Consensus Standard ANSI/NCSL Z540-1-1994, November 21, 2000

7. APPENDICES

Appendix A, 12.1 Basis

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APPENDIX A

12.1 Basis

Source	Citation	Requirement	Comments
10 CFR 830.121, Quality Assurance Program	(c)(3)	4.1.1.3	Company response to 10 CFR 830.121, (c)(3)
10 CFR 830.121, Quality Assurance Program	(c)(3)	4.1.1.3.A	Company response to 10 CFR 830.121, (c)(3))
10 CFR 830.121, Quality Assurance Program	(c)(3)	4.1.1.3.B	Company response to DOE Order 10 CFR 830.121, (c)(3)
10 CFR 830.121, Quality Assurance Program	(c)(3)	4.1.1.4	Company response to 10 CFR 830.121, (c)(3)
ANSI/NCSL Z540-1-1994, American National Standard for Calibration – Calibration Laboratories and Measuring and Test Equipment – General Requirements	All	4.1.1.1	Summary of calibration requirements of ANSI/NCSL Z540-1-1994
ASME NQA-1-1997, Quality Assurance Requirements for Nuclear Facility Applications, Requirement 12	All	4.1.1.1	Summary of calibration requirements of NQA-1-1997
ASME NQA-1-1997, Requirement 12	100	4.1.1.2	Consensus Requirement (CR)
DOE Order 414.1A, Quality Assurance, Attachment 1	1.a (4)	4.1.1.3	Company response to DOE Order 414.1A, Attachment 1, 1.a (4)
DOE Order 414.1A, Quality Assurance, Attachment 1	1.a (4)	4.1.1.3.A	Company response to DOE Order 414.1A, Attachment 1, 1.a (4)
DOE Order 414.1A, Quality Assurance, Attachment 1	1.a (4)	4.1.1.3.B	Company response to DOE Order 414.1A, Attachment 1, 1.a (4)
DOE Order 414.1A, Quality Assurance, Attachment 1	1.a (4)	4.1.1.4	Company response to DOE Order 414.1A, Attachment 1, 1.a (4)

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APPENDIX A

12.1 Basis

Source	Citation	Requirement	Comments
DOE/RW-0333P, Office of Civilian Radioactive Waste Management Program, Quality Assurance Requirements and Description, Revision 10	All	4.1.1.1	Summary of calibration requirements of DOE/RW-0333P
DOE/RW-0333P	12.2.1.A.1s and 12.2.1.G	4.1.2.1	CR
DOE/RW-0333P	12.2.1.C.2s	4.1.2.2	CR
DOE/RW-033P	12.2.1.A.2s	4.1.2.4	CR
DOE/RW-0333P	12.2.2.1s and 12.2.2.2s	4.1.2.5	
DOE/RW-0333P	12.2.4, 12.2.4.A, and 12.2.4.B	4.1.2.3	CR
PRD-5088, 17.1 Quality Assurance Records	All	4.1.3.1	Summary of records requirements from NQA-1-1997, DOE/RW-0333P, and Company Imposed Requirements